



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re the Application of)
Peter Iwen et al.)
Serial No. 09/580,797)
Filed: May 30, 2000)
For: MATERIALS AND METHODS FOR)
MOLECULAR DETECTION OF CLINICALLY)
RELEVANT, PATHOGENIC FUNGAL SPECIES)

) Group Art Unit: 1634
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) Examiner: J. Goldberg
)
) Response to Paper No. 16
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DECLARATION OF PETER C. IWEN

I, Peter C. Iwen, hereby declare that:

1. I am a citizen of the United States and reside at 6006 Lafayette Ave, Omaha, NE 68132.
2. I received a B.S. degree in Bacteriology from North Dakota State University, and a M.S. degree in Medical Microbiology and Ph.D. degree in Medical Sciences (Infectious Diseases): Internal Medicine, from the University of Nebraska Medical Center.
3. I have over 20 years of experience in the field of microbiology, my particular area of expertise being in infectious disease.
4. I am the author or co-author of over 30 scientific articles on the subjects of medical microbiology, immunology, and medicine. A list of these articles is set forth in my curriculum vitae, attached hereto. My current areas of research include fungal pathogen research.
5. I am a co-inventor of the subject matter disclosed and claimed in U.S. Patent Application Serial No. 09/580,797, entitled "MATERIALS AND METHODS FOR MOLECULAR DIAGNOSIS OF CLINICALLY RELEVANT, PATHOGENIC FUNGAL SPECIES." (hereinafter "the '797 application").

Statements Regarding Issues Related to Obviousness

6. I have read and am familiar with the Official Action dated July 25, 2002, in the '797 application. I understand the nature of the rejections made by the Examiner concerning obviousness. I have also read the prior art references relied on in support of the rejection of the claims. Specifically, these claim rejections and the cited prior art are as follows:

Claims:

2-4, 20

Cited Prior Art

White et al. (PCR Protocols: A Guide to Methods and Applications, pages 315-322, 1990) and Beck, US Patent 5,827,695, in view of Borsuk et al. (Acta Biochimica Polionica, Vol. 41:73-77, 1994) and Nikkuni et al. (J. Gen. Appl. Microbiol. 44:225-230, 1998) and Pazoutova (GenBank Accession No. AJ001331 (August 1997) and Peterson (GenBank Accession No. U65306 (May 1997) and Aguirre et al. (GenBank Accession No. U93683 (May 1997) and further in view of Sandhu et al. US Patent 5,707,802.

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White et al. and Beck in view of Borsuk et al. and Nikkuni et al. and Pazoutova and Peterson and Aguirre et al. and further in view of Nelson et al., US Patent 5,827,656.

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White et al. and Beck et al. in view of Borsuk et al. and

Nikkuni et al. and
Pazoutova and Peterson
and Aguirre et al. and
further in view of
Sandhu et al. and Wang
et al., US Patent
5,876,977.

21

White et al. and Beck
in view of Borsuk et
al. and Nikkuni et al.
and Pazoutova and
Peterson and Aguirre
et al. and further in
view of Sandhu et al.
and in further view of
Felgner et al., US
Patent 6,165,720.

7. As exemplified in the specification, my co-inventors and I have devised an improved method for diagnosing pathogenic fungal infection, and further, for differentiating infectious fungal species. The improved method comprises identification of species specific regions which are isolated using PCR amplification of conserved regions. Briefly, in order to provide improved methods for differential fungal pathogen diagnosis, a sample from a patient suspected of having a fungal infection is provided. Two oligonucleotide primers, SEQ ID NO:1 and SEQ ID NO:2 are added which bracket the hypervariable region on the ITS nucleic acid, if present, in the fungal nucleic acid containing sample. The sequence between the primers is amplified and a detectably labeled probe which is directed to a portion of the hypervariable region bracketed by the primers is used to identify the fungal species.

8. None of the references cited by the Examiner teach a primer set which comprises SEQ ID NO:2. The Examiner asserts that the primers of White et al. are functionally equivalent

to the instantly claimed primer set of SEQ ID NO:1 and 2, and thus concludes that the instantly claimed methods are obvious over White et al. It is respectfully submitted that the primers of White et al. are not functionally equivalent to the instantly claimed primer set of SEQ ID NO:1 and 2, as the following data will show.

9. Presented herein as Exhibit A are the results of PCR amplification comparing the primer set of White et al., and SEQ ID NOS: 1 and 2 of the instant application. The claims have been amended and recite a method and primer set which can amplify *A. flavus*, *A. fumigatus*, *A. nidulans*, and *A. terreus*. Exhibit A shows an agarose gel and ethidium bromide staining of PCR products. Lanes 1 and 5, *A. flavus*; Lanes 2 and 6, *A. fumigatus*; Lanes 3 and 7, *A. nidulans*; Lanes 4 and 8, *A. terreus*; and Lane MKR, 100 bp DNA ladder. Primer pairs tested include ITS1th (5'- GGAAGTAAAAGTCGTAACAAGG-3')/ ITS4th (5'- GTATCCCTACCTGATCCGAGG-3'), designated as SEQ ID #1 and SEQ ID #2, respectively and ITS1 (5'-TCCGTAGGTGAACCTGCG-3')/ ITS4 (5'-TCCTCCGCTTATTGATATGC-3'), White et al.

10. From this Experiment, it is clear that the primer set of White et al. is not the functional equivalent of the instantly claimed primer set. In the gel shown in Exhibit A, *A. terreus* was amplified by the primer set of the instant invention, but was not amplified by the primer set of White et al. Also, *A. flavus*, *A. nidulans* were strongly amplified by the primer set of the instant invention, but only weakly amplified by the primer set of White et al. The strength of the signal generated by the amplicon could be a significant factor in accurately diagnosing a particular type of fungal infection. Consequently, the primer set of White et al. would be incapable of diagnosing *A. terreus* infection, and further would most likely not provide accurate diagnosis for *A. flavus* and *A. nidulans*.

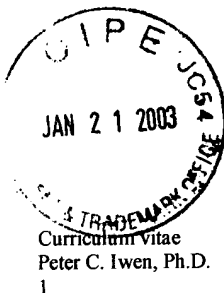
11. Thus, in light of the experimental evidence provided herewith, it is clear that Applicants primer set and methods are surprisingly superior than those described by White et al. Accordingly, it cannot be reasonably maintained that the

instantly claimed subject matter is rendered obvious by the prior art relied on by the Examiner.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued thereon.

12/18/02
DATE

Peter C. Iwen
Peter C. Iwen, Ph.D.



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CURRICULUM VITAE

September 2002

NAME IN FULL: Peter C. Iwen, M.S., Ph.D., M(ASCP), SM(NRM), CLS/M

SOCIAL SECURITY NO: 502-60-5133

ADDRESS: University of Nebraska Medical Center
Department of Pathology and Microbiology
686495 Nebraska Medical Center
Omaha, NE 68198-6495
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E-mail: piwen@unmc.edu

PLACE OF BIRTH: Fargo, North Dakota

EDUCATION:

1997-01	Ph.D., Medical Sciences (Infectious Diseases): Internal Med., University of Nebraska Medical Center, Omaha, NE Thesis, "Characterization of the internal transcribed spacer regions of the rDNA gene complex of human fungal pathogens", September 2001; Advisor, M.E. Rupp, M.D.
1979-82	M.S., Medical Microbiology, University of Nebraska Medical Center; Omaha, NE Thesis, "Treatment of experimental pulmonary cryptococcosis in the immunosuppressed mice with ketoconazole and amphotericin B". December 1982; Advisor, N.G. Miller, Ph.D.
1972-76	B.S., Bacteriology, North Dakota State University; Fargo, ND

POST-DEGREE AND CONTINUING EDUCATION TRAINING

02/1998 to 01/2001	Fulfilled re-certification requirements with the National Certification Agency for Medical Laboratory Personnel as a Clinical Laboratory Scientist in Microbiology. CLS/M Current through January 2004
07/1993 to 06/1998	Fulfilled re-certification requirements with the National Registry of Microbiologists as a Specialist Microbiologist in Public Health and Medical Laboratory Microbiology. SM(NRM) Current through December 2003.

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ACADEMIC APPOINTMENTS:

1996-present	Assistant Professor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE
1986-2000	Instructor, Iowa Western Community College, Nursing Department, Council Bluffs, IA
1993-96	Instructor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE
1988-93	Courtesy Instructor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE

CERTIFICATIONS AND LICENSES:

1992-present	Clinical Laboratory Scientist in Microbiology. The National Certification Agency for Medical Laboratory Personnel. CLS/M
1988-present	Specialist Microbiologist in Public Health and Medical Laboratory Microbiology. The National Registry of Microbiologists, American Academy of Microbiology. SM(NRM)
1984-present	Microbiologist. American Society of Clinical Pathologists. M(ASCP)

GRANT/CONTRACT SUPPORT:

10/02 to 09/03	"Development of a microchip for the identification of fungal pathogens" Transgenomic, Inc. Principal Investigator, Peter C. Iwen (\$50,000)
09/02 to 08/03	"Molecular characterization and pathogenesis of <i>Francisella tularensis</i> " Provisional PIs, Mike Meagher/ (\$100,000) Steve Hinrichs Co-Investigator Peter C. Iwen
07/02 to 09/03	"Bioterrorism laboratory service agreement" Principal Investigator Steve Hinrichs (\$900,000) Co-Investigator Peter C. Iwen
01/02 to 10/02	"Practice guideline for treatment of suspected and proven candidiasis with fluconazole in non-neutropenic patients" Pfizer Pharmaceutical Principal Investigator, Phil Smith (\$6,500) Co-Investigator Peter C. Iwen

- 09/01 to 12/02 "A phase II, randomized, parallel, placebo-controlled, double-blind, multicenter efficacy and safety study of ramoplanin and placebo in neutropenic oncology patients identified as asymptomatic carriers of vancomycin-resistant *Enterococcus* (VRE)
IntraBiotics Pharmaceuticals, Inc.
Principal Investigator, Julie Vose (\$14,500)
Co-Investigator **Peter C. Iwen**
- 09/01 to 08/02 "Evaluation of the WAVE System to identify fungal pathogens"
Transgenomic, Inc.
Principal Investigator, Steven H. Hinrichs (\$50,000)
Co-Investigator **Peter C. Iwen**
- 09/01 to 03/02 "Dade MicroScan clinical study: dried overnight cation-adjusted antimicrobials for gram-negative organisms, Summer 2001"
Dade Bering, MicroScan Division
Principal Investigator, **Peter C. Iwen** (\$14,700)
- 08/01 to 12/02 "Comparison of hand bioburden in response of various hand hygiene practices"
UNMC Clinical Research Center
Principal Investigator, Mark Rupp (\$4,000)
Co-Investigator **Peter C. Iwen**
- 04/01 to 04/03 "Chemotherapy alliance for neutropenics and the control of emerging resistance (CANCER) surveillance program"
The Jones Group
Principal Investigator, **Peter C. Iwen** (\$18,000)
- 11/00 to 12/02 "Phase III, randomized, evaluation committee-blinded study to assess the safety and efficacy of topical administration of MBI 226 1.0% gel versus standard medical care in patients undergoing non-cuffed, short-term arterial and/or central venous catheterization"
Omnicare Clinical Research
Principal Investigator, Austin Thompson (\$300,000)
Co-Investigator **Peter C. Iwen**
- 07/00 to 06/01 "Faculty education support grant"
UNMC College of Medicine
Principal Investigator, **Peter C. Iwen** (\$1,600)
- 06/00 to 06/01 "Application of a new polymerase chain reaction technique for rapid detection and identification of fungal pathogens"

	Merck & Co., Inc. Principal Investigator,	Peter C. Iwen	(\$66,540)
06/00 to 06/01	"Dade MicroScan clinical trial Conventional Antibiotic Qualification 8" Dade Behring, MicroScan Division Principal Investigator,	Peter C. Iwen	(\$32,500)
11/99 to 03/01	"Influenzae surveillance program" R.W. Johnson Pharmaceutical Research Institute Principal Investigator,	Peter C. Iwen	(\$5,000)
09/99 to 12/00	"Enhanced laboratory preparedness" Nebraska Department of Health and Human Services Principal Investigator, Contract Support,	James Wisecarver Peter C. Iwen	(\$140,825)
09/99 to 11/99	"Historic control study of the efficacy of standard therapy in acute aspergillosis to allow comparison with the efficacy of voriconazole" Pfizer Corporation Principal Investigator, Contract Support,	Elizabeth Reed Peter C. Iwen	(\$3,700)
09/99 to 02/00	"Outcomes experience of patients with invasive aspergillosis treated with amphotericin B, lipid formulations of amphotericin B, and/or itraconazole" Merck & Co., Inc Principal Investigator, Co-Investigator,	Edward Dominguez Peter C. Iwen	(\$24,000)
08/99 to 03/00	"North American Zyvox (linazolid) antimicrobial potency study" The Clinical Pharmacokinetics Laboratory Principal Investigator,	Peter C. Iwen	(\$2,250)
07/99 to 11/99	"Moxifloxacin regional and national in vitro susceptibility of common respiratory tract pathogens" Bayer Corporation Principal Investigator,	Peter C. Iwen	(\$5,000)
02/99 to 12/99	"Improving the diagnosis of invasive aspergillosis in immuno-compromised patients" The Liposomal Company Principal Investigator,	Peter C. Iwen	(\$5,000)

10/98 to 06/99	<p>“The impact of <i>Lactobacillus casei</i> GG on the GI function in short bowel syndrome”</p> <p>ConAgra, Inc.</p> <p>Principal Investigator, Judith D. Sondheimer (\$2,000)</p> <p>Co-Investigator, Peter C. Iwen</p>
07/98 to 07/00	<p>A comparison of the Arrowg+ and III antimicrobial surface treated, triple-lumen, central venous catheters vs. standard-triple lumen catheters in a randomized, double-blinded multi center trial”</p> <p>Arrow International, Inc.</p> <p>Principal Investigator, Mark E. Rupp (\$150,000)</p> <p>Contract Support Peter C. Iwen</p>
07/98 to 06/99	<p>“Faculty education support grant”</p> <p>UNMC College of Medicine</p> <p>Principal Investigator, Peter C. Iwen (\$1,000)</p>
07/98 to 12/98	<p>“Enterohemorrhagic <i>E.coli</i> prevalence study”</p> <p>State of Nebraska</p> <p>Principal Investigator, Paul D. Fey (\$7,000)</p> <p>Co-Investigator, Peter C. Iwen</p>
02/98 to 12/98	<p>“Universal swab equivalency study”</p> <p>GenProbe, Inc.</p> <p>Principal Investigator, Peter C. Iwen (\$24,800)</p> <p>Co-Investigator, Steven H. Hinrichs</p>
07/97 to 06/98	<p>“Enteric decontamination with bacitracin and bismuth subsalicylate in patients colonized with VRE”</p> <p>UNMC Seed Research Grant</p> <p>Principal Investigator, Mark E. Rupp (\$7,500)</p> <p>Co-Investigator, Peter C. Iwen</p>
02/97 to 02/98	<p>“Dried overnight gram-positive identification clinical trial”</p> <p>Dade MicroScan International</p> <p>Principal Investigator, Peter C. Iwen (\$5,000)</p>
07/96 to 06/97	<p>“Study of contamination in non-vented closed enteral feeding systems”</p> <p>Clintec Technologies, Inc.</p> <p>Principal Investigator, Mark E. Rupp (\$15,000)</p> <p>Contract Support Peter C. Iwen</p>

07/96 to 12/96	"National broad spectrum-lactamase surveillance trial." University of Iowa Hospitals and Clinic. Principal Investigator, Ron Jones Co-Investigator, Peter C. Iwen (\$1,500)		
07/93 to 06/94	"Evaluation of the PACE 2C to detect <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> " Gen-Probe, Inc. Principal Investigator, Gail Woods (\$34,000) Co-Investigator, Peter C. Iwen		

PATENTS:

U.S. Application No. 09/580,797 (pending)

COLLECTIONS:

American Type Culture Collection

8/98	<i>Aspergillus ustus</i>	ATCC 201953
1/99	<i>Gymnascella hyalinospora</i>	ATCC 204275
1/99	<i>Cylindrocarpon lichenicola</i>	ATCC 204306
2/00	<i>Candida glabrata</i>	ATCC MYA-296
7/01	<i>Exiguobacterium aurantiacum</i>	ATCC BAA-333

NCBI GenBank Sequences

2/99	<i>Gymnascella hyalinospora</i>	(VAMH 7366)	ITS1-5.8S-ITS2	AF129853
2/99	<i>Gymnascella hyalinospora</i>	(ATCC 204275)	"	AF129854
2/99	<i>Cladophialophora bantiana</i>	(UTHSC94-986)	"	AF131079
3/99	<i>Cylindrocarpon lichenicola</i>	(ATCC204306)	ITS1-5.8S-ITS2	AF133843
5/99	<i>Aspergillus fumigatus</i>	(ATCC 36607)	"	AF138288
5/99	<i>Aspergillus terreus</i>	(ATCC 16792)	"	AF138290
5/99	<i>Aspergillus flavus</i>	(ATCC 16883)	"	AF138287
5/99	<i>Emmerciella nidulans</i>	(ATCC 10074)	"	AF138289
5/99	<i>Aspergillus niger</i>	(ATCC 16888)	"	AF138904
5/99	<i>Aspergillus ustus</i>	(ATCC 201953)	"	AF157507
6/99	<i>Cryptococcus neoformans</i>	(ATCC 32045)	"	AF162916
6/99	<i>Ajellomyces capsulatus</i>	(ATCC 12700)	"	AF156892
6/99	<i>Histoplasma duboisii</i>	(ATCC 24294)	"	AF162917
7/99	<i>Fusarium oxysporum</i>	(ATCC 48112)	"	AF165875
7/99	<i>Fusarium moniliforme</i>	(ATCC 48843)	"	AF165873
7/99	<i>Nectria haematococca</i>	(ATCC 62877)	"	AF165874
7/99	<i>Candida glabrata</i>	(ATCC 15545)	"	AF167993
7/99	<i>Cylindrocarpon destructans</i>	(UAMH 4907)	"	AF172261
7/99	<i>Candida lusitanae</i>	(ATCC 66035)	"	AF172262

8/99	<i>Pseudallescheria boydii</i>	(patient)	“	AF181558
9/99	<i>Blastoschizomyces capitatus</i>	(patient)	“	AF183911
9/99	<i>Ajellomyces dermatitidis</i>	(patient)	“	AF183912
1/00	<i>Candida albicans</i>	(ATCC 28516)	“	AF217609
1/00	<i>Lactobacillus rhamnosus</i>	(ATCC 53103)	16S-ITS-23S	AF217610
3/00	<i>Malassezia furfur</i>	(ATCC 44344)	ITS1-5.8S-ITS2	AF246896
3/00	<i>Issatchenkia orientalis</i>	(ATCC 6258)	“	AF246989
7/00	<i>Candida tropicalis</i>	(ATCC 750)	“	AF287910
7/00	<i>Candida parapsilosis</i>	(ATCC 22019)	“	AF287909
8/00	<i>Yersinia enterocolitica</i>	(ATCC 27729)	16S-ITS-23S	AF293850
8/00	<i>Bacillus cereus</i>	(clinical isolate)	“	AF293851
9/00	<i>Bacillus anthracis</i>	(Pasteur strain)	“	AY008265
5/01	<i>Sporothrix schenckii</i>	(ATCC 14284)	ITS1-5.8S-ITS2	AF364061
9/01	<i>Exiguobacterium auranticum</i>	(ATCC BAA-333)	16S rDNA	AY047481
12/01	<i>Rhizomucor pusillus</i>	(patient)	ITS1-5.8S-ITS2	AF461764
12/01	<i>Pichia jadinii</i>	(patient)	“	AF458091

OTHER APPOINTMENTS/POSITIONS:

Nonacademic appointments

2001-present	Biosafety Officer Univer. NE Med. Ctr./ Univer. NE at Omaha/ NE Health Systems
1997-present	Associate Director, Nebraska Public Health Laboratory
1997-present	Special Microbiology Projects Coordinator, Nebraska Health System's Clinical Microbiology Laboratory
1994-97	Clinical Projects Coordinator, University Hospital's Clinical Microbiology Laboratory
1986-93	Supervisor, Pathology and Microbiology University of Nebraska Medical Center
1983-86	Technical Supervisor, Medical Microbiology University of Nebraska Medical Center
1980-83	Laboratory Technologist, Medical Microbiology University of Nebraska Medical Center
1978-80	Laboratory Technician, Medical Microbiology University of Nebraska Medical Center

Part-time positions

1982-96	Technologist, Clinical Microbiology Laboratory, University Hospital, Omaha
1980-82	Laboratory Technologist, Animal Vaccine Laboratories, Council Bluffs, IA

CONSULTING POSITIONS:

Academic

- | | |
|--------------|---|
| 1992-present | Midwest Student Medical Research Forum,
Abstract Judge, American Medical Association |
| 1991-present | Student Research Forum,
Abstract Judge, UNMC Center for Continuing Education |

Government

- | | |
|---------|--|
| 1981-97 | Consultant
University Hospital's Clinical Microbiology Laboratory |
|---------|--|

Industry

- | | |
|--------------|---|
| 2001-present | Transgenomic, Inc., Omaha, NE |
| 1983-86 | Porci-Tec Labs, Inc., Avoca, IA |
| 1982-86 | Modern Veterinary Products, Inc., Ralston, NE |

Editorial duties

- | | |
|--------------|---|
| 2000-present | Invited reviewer, <i>Medical Mycology</i> |
| 1997-present | Invited reviewer, <i>Diagnostic Microbiology and Infectious Disease</i> |
| 1994-present | Invited reviewer, <i>Clinical Infectious Diseases</i> |
| 1994-present | Invited reviewer, <i>Infection Control and Hospital Epidemiology</i> |

MILITARY SERVICE:

None. No obligation

HONORS AND AWARDS:

- | | |
|------|---|
| 1998 | Travel Award to ASM General Meeting,
Dade MicroScan, Inc., West Sacramento, CA. |
| 1997 | Scherago-Rubin Award,
American Society for Microbiology, Washington, D.C. |
| 1995 | Travel Award to ASM General Meeting,
Dade MicroScan Inc., West Sacramento, CA. |
| 1994 | Travel Award to ASM General Meeting,
Gen Probe Inc, San Diego, CA. |
| 1991 | Certificate of Merit for Excellence in Teaching,
American Medical Student Association |
| 1990 | Travel Award to ASM Annual Meeting,
DIFCO Laboratories, Ann Arbor, Mich. |
| 1987 | Nominee for Outstanding Service to Allied Health Profession,
First year Physician Assistant Students |

MEMBERSHIPS AND OFFICES IN PROFESSIONAL SOCIETIES:

2002-present	Full member,	American Biological Safety Association
2001-present	Delegate member,	Association of Public Health Laboratories
1985-present	Full member,	American Society for Microbiology
1985-present	Associate member,	American Society for Clinical Pathologists

COMMITTEE ASSIGNMENTS:

2001 to present	Member,	UNMC Safety Committee University of Nebraska Medical Center, Omaha
2001 to present	Member,	Institutional Biosafety Committee University of Nebraska Medical Center, Omaha
2001 to present	Member,	Bioterrorism Steering Committee Nebraska Health Systems, Omaha
2001 to present	Member,	Policy and Planning Committee Association of Public Health Laboratories, Washington, D.C.
1998 to present	Member,	Infection Control Committee Nebraska Health Systems, Omaha
1986 to 1998	Member,	Infection Control Committee University Hospital, Omaha

BIBLIOGRAPHY:

Articles published in scholarly journals

Iwen, P.C., N.G. Miller, and H.W. McFadden, Jr. 1984. Treatment of murine pulmonary cryptococcosis with ketoconazole and amphotericin B. *J. Infect. Dis.*, 149:650.

Iwen, P.C. and N.G. Miller. 1986. Enhancement of ketoconazole across the blood-brain barrier of mice by dimethyl-sulfoxide. *Antimicrob. Agents Chemother.*, 30:617-618.

Iwen, P.C., S.J. Booth, and G.L. Woods. 1989. Comparison of media for screening of diarrhetic stools for the recovery of *Clostridium difficile*. *J. Clin. Microbiol.*, 27:2105-2106.

Records, R.E. and **P.C. Iwen**. 1989. Experimental bacterial endophthalmitis following extracapsular lens extraction. *Experiment. Eye Res.*, 49:729-737.

Woods, G.L. and **P.C. Iwen**. 1990. Comparison of a dot immunobinding assay, latex agglutination, and cytotoxin assay for laboratory diagnosis of *Clostridium difficile*-associated diarrhea. *J. Clin. Microbiol.*, 28:855-857.

Tritz, D.M., **P.C. Iwen** and G.L. Woods. 1990. Evaluation of MicroScan™ for identification of *Enterococcus* species. J. Clin. Microbiol., 28:1477-1478.

Iwen, P.C., T.M.H. Blair, and G.L. Woods. 1991. Comparison of the Gen-Probe PACE 2 System, direct fluorescent-antibody and cell culture for detecting *Chlamydia trachomatis* in cervical specimens. Amer. J. Clin. Path., 95:578-582.

Sahm, D.F., S. Boonlayangoor, **P.C. Iwen**, J.L. Baade, and G.L. Woods. 1991. Factors influencing determination of high-level amino glycoside resistance in *Enterococcus faecalis*. J. Clin. Microbiol., 29:1934-1939.

Iwen, P.C., E.C. Reed, J.O. Armitage, P.J. Bierman, A. Kessinger, J.M. Vose, M.A. Arneson, B.A. Winfield, and G.L. Woods. 1993. Nosocomial invasive aspergillosis in lymphoma patients treated with bone marrow or peripheral stem cell transplants. Infect. Control Hosp. Epidemiol., 14:131-139.

Iwen, P.C. 1993. Nosocomial aspergillosis in lymphoma patients (reply). Infect. Control Hosp. Epidemiol., 14:509.

Iwen, P.C., J.C. Davis, E.C. Reed, B.A. Winfield, and S.H. Hinrichs. 1994. Airborne fungal spore monitoring in a protective environment during hospital construction and correlation with an outbreak of invasive aspergillosis. Infect. Control Hosp. Epidemiol., 15:303-306.

Iwen, P.C., D.M. Kelly, E.C. Reed, and S.H. Hinrichs. 1995. Invasive infection due to *Candida krusei* in immunocompromised patients not treated with fluconazole. Clin. Infect. Dis. 20:342-347.

Iwen, P.C., R.A. Walker, K.L. Warren, D.M. Kelly, S.H. Hinrichs, and J. Linder. 1995. Evaluation of a nucleic acid-based test for simultaneously detecting *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in endocervical specimen. J. Clin. Microbiol., 33:2587-2591.

Iwen, P.C., D.M. Kelly, J. Linder, and S.H. Hinrichs. 1996. Revised approach for identification and detection of ampicillin and vancomycin resistance in *Enterococcus* species by using MicroScan panels. J. Clin. Microbiol., 34:1779-1783.

Iwen, P.C., R.A. Walker, K.L. Warren, D.M. Kelly, J. Linder, and S.H. Hinrichs. 1996. Effect of off-site transportation on detection of *Neisseria gonorrhoeae* in endocervical specimens. Arch. Pathol. Lab. Med., 120:1019-1022.

Iwen, P.C., E.A. Dominguez, D.M. Kelly, J. Linder, K.D. Patil, M.E. Rupp, and S.H. Hinrichs. 1997. Change in prevalence and antibiotic resistance in *Enterococcus* species isolated from blood cultures over an eight year period. Antimicro. Agents Chemother., 41:494-495.

Iwen, P.C., M.E. Rupp, and S.H. Hinrichs. 1997. Invasive mold sinusitis: seventeen cases in immunocompromised patients and review of the literature. *Clin. Infect. Dis.*, 24: 1178-1184.

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Iwen, P.C., R. Rennie, D. Ballou, J. Johnston, S. Connell, and B. Zimmer. 2001. Multicenter evaluation of moxifloxacin and gatifloxacin comparing a MicroScan dried overnight panel with an NCCLS reference panel. 101st General Meeting of the American Society for Microbiology, Orlando, FL, May 21, 2001.

Iwen, P.C. 2002. The role of molecular mycology in clinical medicine. Focus on Fungal Infections 12, Phoenix, AZ, March 21, 2002.

Iwen, P.C., A.G. Freifeld, T.A. Bruening, and S.H. Hinrichs. 2002. Evaluation of the ESP blood culture system with a panfungal PCR assay for the detection of fungal pathogens in human blood. 102nd General Meeting of the American Society for Microbiology, Salt Lake City, UT May 21, 2002.

Submissions

Shearon, E.C., S.H. Hinrichs, D.A. Sutton, M.G. Rinaldi, D.L. McCarthy, D. Sudan, and **P.C. Iwen.** 2002. Correlation of susceptibility testing with clinical response in patients without hematologic malignancies who develop candidemia caused by *Candida lusitanae*. Clin. Infect. Dis. (Manuscript)

Stickle, D.F., D.A. McKenzie, J.A. Landmark, S.J. Pirruccello, G.A. Post, **P.C. Iwen,** and S.H. Hinrichs. 2002. Effect of sterilizing gamma irradiation on bloodspot newborn screening tests and on whole blood cyclosporine and FK-506 measurements. Amer. J. Clin. Pathol. (Manuscript)

Iwen, P.C. 2002. Molecular detection and typing of fungal pathogens. Clinics in Laboratory Medicine. (Book chapter)

TEACHING ACTIVITIES: 2001-2002
Contact hours (ch) per calendar year

Lectures in team-taught courses

Introductory mycology	Medical	M-ID 630	1.5 ch
Mycology board review	Medical	M-ID 630	1.5
Parasitology board review	Medical	M-ID 630	1.5
Streptococci	PA/Pharm D	MM 550	2
Chlamydia	PA/Pharm D	MM 550	1
Introductory mycology	PA/Pharm D	MM 550	1
Antifungal agents	PA/Pharm D	MM 550	1
Cutaneous mycoses	PA/Pharm D	MM 550	1
True systemic mycoses	PA/Pharm D	MM 550	1
Opportunistic mycoses	PA/Pharm D	MM 550	1

Laboratory coordinator and instructor in team-taught courses

Immunological reagents	Medical	M-ID 630	2 ch
POPS: Tetanus	Medical	M-ID 630	2
POPS: Hypersensitivity	Medical	M-ID 630	2
Microbiological techniques	Medical	M-ID 630	4
Introductory mycology	Medical	M-ID 630	3
Diagnostic virology	Medical	M-ID 630	2
Diagnostic parasitology	Medical	M-ID 630	3
Blood cultures	Medical	M-ID 630	4
Urinary tract infections	Medical	GU core	4
Sexually transmitted diseases	Medical	GU core	2
Diseases of the lower GI	Medical	GI core	2

Problem-based learning/small group facilitator

PBL-case 1	Medical	M-ID 630	4 ch
PBL-case 2	Medical	M-ID 630	5
PBL-case 3	Medical	M-ID 630	5
PBL-case 4	Medical	M-ID 630	5
PBL-case 5	Medical	M-ID 630	5
PBL-case 1	Medical	Hematology	5
PBL-case 2	Medical	Hematology	5

Course coordinator

Medical Microbiology Laboratory	PA	MM 511	60 ch
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Graduate students and resident training

Infectious Diseases residency training and mentor on research projects

Curriculum vitae
Peter C. Iwen, Ph.D.
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Pathology residency training and mentor on research projects

Local, regional, and national educational activities

Contributor to the "Nebraska Public Health Newsletter"

Participant in local Infectious Disease Weekly Conference

Regional consultant for environmental biological monitoring

Participant in local Infectious Disease Journal Club

Contributor and consultant to numerous articles in "UNMC Today"

Presentations to civic clubs and other organizations

Numerous television, newspaper, and radio interviews on microbiology and infectious diseases topics